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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,425	03/17/2004	Bonnie L. Bassler	4555-128.1.1 US	3998
26817	7590	06/10/2009		
MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A. 29 THANET ROAD, SUITE 201 PRINCETON, NJ 08540			EXAMINER JOIKE, MICHELE K	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 06/10/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/802,425	<b>Applicant(s)</b> BASSLER ET AL.	
	<b>Examiner</b> MICHELE K. JOIKE	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36, 39-48, 99 and 100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 99 and 100 is/are allowed.
- 6) ☒ Claim(s) 1, 3-36, 39, 40 and 42-48 is/are rejected.
- 7) ☒ Claim(s) 2 and 41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed February 23, 2009. Claims 1-36, 39-48 and 99-100 are pending in the instant application and are examined. Any rejection of record in the previous Office Action, mailed November 26, 2008 that is not addressed in this action has been withdrawn. Because this Office Action introduces new rejections other than those set forth in the previous Office Action, and are not necessitated by amendment, this Office Action is **Non-Final**.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-36, 39-40, 42-47 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7,326,542.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

Art Unit: 1636

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US 7,326,542 (especially columns 3, 4, 10, 12, 14, 15, 20, 22, and 27-29) teaches a method for identifying a compound that regulates the activity of a signaling factor (autoinducer-2) by contacting the signaling factor with the compound, measuring the activity of the signaling factor in the presence of the compound and comparing the activity of the signaling factor obtained in the presence of the compound to the activity of the signaling factor obtained in the absence of the compound and identifying a compound that regulates the activity of the signaling factor. The autoinducer-2 can be 4,5-dihydroxy-2,3-pentanedione. The method can be performed *in vivo* or *in vitro*, and the activity of the autoinducer can be increased or decreased, as the compound can act as an activator or inhibitor. (Since there is no definition of competitive or suicide inhibitor in the specification, it is assumed that any inhibitor anticipated by the reference can be used.) The compound can be a polypeptide, small molecule or nucleic acid. The method can also be used to identify an analog that regulates activity of a non-homoserine lactone autoinducer-2. Other autoinducer-2s are anticipated by the reference, such as homocysteine. The autoinducer-2 can be endogenous or exogenous. The reference also teaches analogs of autoinducer-2, such as a ribose derivative. Bacteria used include *Vibrio harveyi*, including strains BB170 and MM32. These reporter strains produce light in response to regulation of activity of autoinducer-2. Either LuxN, LuxS or both genes can be mutated. The autoinducer-2 can form a

Art Unit: 1636

complex with a receptor and the complex can be bound to solid support medium, including a microtiter dish.

The reference also teaches a method for detecting an autoinducer-associated bacterial biomarker by contacting at least one bacterial cell with an autoinducer molecule under conditions and for such time as to promote induction of a bacterial biomarker and detecting the bacterial biomarker. Additionally, a method for detecting an autoinducer-associated bacterial biomarker by contacting at least one bacterial cell with an autoinducer molecule under conditions and for such time as to promote induction of a bacterial biomarker is taught.

This is a new rejection not necessitated by amendment.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an analog comprising a ribose derivative. The claims read on a broad genus of ribose derivatives.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicants were in possession of the claimed invention. In the instant case, the specification does not sufficiently describe a representative number of ribose derivatives by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a ribose derivative by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings of autoinducer-2 as a ribose derivative. The specification does not describe any other ribose derivatives or any of the characteristics that would make a ribose derivative. It is unclear how close structurally and functionally to ribose the derivative needs to be. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses autoinducer-2 as a ribose derivative.

The state of the art at the time of filing does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the art that allows one to envision a representative number of ribose derivatives by disclosing structural or functional features of ribose derivatives so that one of skill in the art could envision the claimed invention. Thus the skilled artisan

Art Unit: 1636

cannot consult the art at the time of filing to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the state of the art at the time of filing teaches a structure-function relationship for a representative number of ribose derivatives. As a result, the skilled artisan would not be able to envision the claimed invention. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

This is a new rejection not necessitated by amendment.

***Allowable Subject Matter***

Claims 2 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 99 and 100 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

Art Unit: 1636

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/  
Examiner, Art Unit 1636

Michele K. Joike  
Examiner  
Art Unit 1636